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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,931	10/29/2003	Margaret Aleles	JBPS001NP	7043
27777	7590	04/13/2010	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			PORTER, RACHEL L	
ART UNIT	PAPER NUMBER			
	3626			
NOTIFICATION DATE	DELIVERY MODE			
04/13/2010	ELECTRONIC			

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jnjuspatent@corus.jnj.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/695,931	<b>Applicant(s)</b> ALELES ET AL.
	<b>Examiner</b> RACHEL L. PORTER	<b>Art Unit</b> 3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 July 2009.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 1-56 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 57-64 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

1. This communication is in response the election mailed 1/14/10 . Claims 1-64 are pending. Claims 1-56 have been withdrawn from further consideration. Claims 57-64 are presented for examination.

***Information Disclosure Statement***

2. The IDS's filed 2/24/04, 3/11/2005 and 7/20/09 have been considered by the examiner.

***Election/Restrictions***

3. In the reply filed 1/14/10, applicant requested clarification of the status of Claims 47-51. On a telephone message left March 24, 2010, it was explained that claims 47-51 would be Group V ( drawn to methods of diagnostic testing through sampling of nonliquid body material, classified 600/562).

4. Applicant chose to maintain the election without traverse of Group IV, Claims 57-64 in the reply filed on 1/14/10.

***Claim Rejections - 35 USC § 101***

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 57-64 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Based on Supreme Court precedent and recent Federal Circuit decisions, the Office's guidance to examiners is that a §101 process must (1) be tied to a particular machine or apparatus or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780,787-88 (1876). If neither of these requirements is met by the claim, the method is not a patent eligible process under §101 and should be rejected as being directed to nonstatutory subject matter.

There are two corollaries to the machine-or-transformation test. First, a mere field-of-use limitation is generally insufficient to render an otherwise ineligible method claim patent- eligible. This means the machine or transformation must impose meaningful limits on the method claim's scope to pass the test. Second, insignificant extra-solution activity will not transform an unpatentable principle into a patentable process. This means reciting a specific machine or a particular transformation of a specific article in an insignificant step, such a data gathering or outputting, is not sufficient to pass the test.

Claims 57 fails to recite a particular machine or apparatus used to perform the steps of the recited method.

Dependent claims 58-64 contain similar deficiencies and fail to correct the

deficiencies of claim 64, and are therefore also rejected.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 57,60, and 62-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Douglas et al (US 6,039,688).

[claim 57] Douglas discloses a method of providing a personalized wellness program to a customer/user (col. 5, line 54-59), the method comprising:

- a) obtaining personal information from a customer; (col. 6, lines 14-26; col. 6, lines 58- col. 7, line)
- b) obtaining objective information comprising a stress measurement from the customer; (col. 6, lines 58- col. 7, line 5—vitals including blood pressure , and stress levels )
- c) using the personal information and the objective information to create a personalized wellness program for the customer; and (col. 7, lines 15-43--information is used to design activities, and generate goals for the patient.
- d) providing the personalized wellness program to the customer, wherein the personalized wellness program comprises a recommendation for a product, service, or activity to improve the customer's stress measurement. (col. 7, lines 54-col. 8, line 5—

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recommended activities and medications (products ) are made for the patient who may access the plan once they log onto the website)

[claim 60] Douglas discloses the method of claim 57 wherein the stress measurement comprises a psychometric measurement. (col. 7, lines 1-4--eating habits; blood pressure; depression)

[claim 62, 63] Douglas discloses method of claim 57 wherein the personalized wellness program comprises a recommendation for a product, activity, or service to decrease stress measurement. (col. 7, lines 31-37; col. 14, lines 54-57—education activities for improving stress levels, decreasing stress affects/decreases hormonal/cortisol stress levels ).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 58-59, 61 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas in view of Kirschbaum et al (Kirschbaum, Clemens, et al. "Salivary Cortisol in Psychobiological Research: An Overview", *Neuropsychobiology* 1989 pp. 150-169.  
--Kirschbaum)

[claims 58, 59 and 64] Douglas discloses the method of claim 57 wherein the stress measurement level of the patient/ customer is checked, (col. 6, lines 58- col. 7, line 5) but does not expressly disclose that the stress measurement is a stress hormone level or that the hormone is cortisol. Douglass also does not disclose measuring/analyzing the stress hormone through salivary samples.

Kirschbaum discloses that the stress hormone, cortisol is considered to be a major indicator of altered physiological states in response to states. (Pg. 150, introduction, par. 2.) Kirschbaum further discloses that salivary samples of the cortisol hormone provide more accurate assay results. (pg. 150, par. 2) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Douglass with the teaching of Kirschbaum to perform stress hormone level testing (e.g. salivary cortisol testing) to assist in determining the stress levels of the patient/customer. As suggested by Kirschbaum, one would have been motivated to include this feature to get more accurate results, which are less invasive to the customer. (Kirschbaum, Pg. 150, introduction, par. 2.)

[claim 61] Douglass discloses the method of claim 57 wherein the stress measurement comprises a psychometric measurement. (col. 7, lines 1-4--eating habits; blood pressure; depression) but does not expressly disclose it also includes a measurement of stress hormone level.

Kirschbaum discloses that the stress hormone, cortisol is considered to be a major indicator of altered physiological states in response to states. (Pg. 150,

introduction, par. 2.) Kirschbaum further discloses that salivary samples of the cortisol hormone provide more accurate assay results. (pg. 150, par. 2) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Douglass with the teaching of Kirschbaum to perform stress hormone level testing (e.g. salivary cortisol testing) to assist in determining the stress levels of the patient/customer. One would have been motivated to include this feature to get more accurate results, which are less invasive to the customer. (Kirschbaum, Pg. 150, introduction, par. 2.), while also providing additional points and goals to target in the wellness program.

### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- Wiegand et al ( US 20020090664A1) discloses a method for measuring stress hormones in mammals.
- Mklas et al (US005304112A ) and August ( 5,681,259) disclose a systems for stress reduction.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL L. PORTER whose telephone number is (571)272-6775. The examiner can normally be reached on M-F, 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rachel L. Porter/  
Examiner, Art Unit 3626